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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,303	04/21/2004	Ralph C. Budd	2317.001A	5666

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/829,303	<b>Applicant(s)</b> BUDD ET AL.	
	<b>Examiner</b> Michail A Belyavskyi	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

*Claims 1-21 are pending.*

### ***Restriction Requirement***

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-4, 7, 9-10 drawn to a method of suppressing the immune system comprising administering an unmodified caspase-8 inhibitor, classified in Class 424, subclass 184.1.
  - II. Claims 1-3, 5-6 and 8 drawn to a method of suppressing the immune system comprising administering a modified caspase-8 inhibitor, classified in Class 424, subclass 184.1.
  - III. Claims 11-14,17 and 19-20 drawn to a method of treating a tumor disease comprising administering an unmodified caspase-8 inhibitor, classified in Class 424, subclass 184.1.
  - IV. Claims 11-13,15-16 and 18 drawn to a method of treating a tumor disease comprising administering a modified caspase-8 inhibitor, classified in Class 424, subclass 184.1.
  - V. Claim 21 drawn to a method of inhibiting the proliferation of peripheral blood lymphocytes comprising administering a caspase-8 inhibitor, classified in Class 424, subclass 184.1.
2. Groups I- V are different methods. These invention are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

3. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### **Species Election**

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4. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

5. If Groups I or II are elected, applicant is required to elect a specific method of suppressing the immune system comprising administering a specific caspase-8 inhibitor wherein the specific caspase-8 inhibitor consists of : A) a specific oligopeptide or polypeptide or a partial sequence of a native protein such as one selected from the group recited in Claim 7; B) has specific origin selected from the group recited in Claim 10.

These species are distinct because the specific method of suppressing the immune system comprising administering a specific caspase-8 inhibitor differ with respect to the specific caspase-8 inhibitor thus each specific method employing a specific caspase-8 inhibitor represents patentably distinct subject matter. Furthermore, the examination of specific caspase-8 inhibitor consists of : A) a specific oligopeptide or polypeptide or a partial sequence of a native protein such as one selected from the group recited in Claim 7; B) has specific origin selected from the group recited in Claim 10 in the method of suppressing the immune system would require different searches in the scientific literature.

In addition, if Group II is elected, Applicant is further required to elect a specific method of suppressing the immune system comprising administering a specific caspase-8 inhibitor wherein the specific modification at the C-terminus of caspase-8 inhibitor comprises modification recited in claim 6.

These species are distinct because the specific method of suppressing the immune system comprising administering a specific caspase-8 inhibitor differ with respect to the specific caspase-8 inhibitor thus each specific method employing a specific caspase-8 inhibitor represents patentably distinct subject matter. Furthermore, the examination of specific caspase-8 inhibitor wherein the specific modification at the C-terminus of caspase-8 inhibitor comprises modification recited in claim 6 in the method of suppressing the immune system would require different searches in the scientific literature.

6. If Groups III or IV are elected, applicant is required to elect a specific method of treating a tumor disease comprising administering a specific caspase-8 inhibitor wherein the specific caspase-8 inhibitor consists of : A) a specific oligopeptide or polypeptide or a partial sequence of a native protein such as one selected from the group recited in Claim 17; B) has specific origin selected from the group recited in Claim 20.

These species are distinct because the specific method of suppressing the immune system comprising administering a specific caspase-8 inhibitor differ with respect to the specific caspase-8 inhibitor thus each specific method employing a specific caspase-8 inhibitor represents patentably distinct subject matter. Furthermore, the examination of specific caspase-8 inhibitor

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consists of : A) a specific oligopeptide or polypeptide or a partial sequence of a native protein such as one selected from the group recited in Claim 17; B) has specific origin selected from the group recited in Claim 20 in the method of treating a tumor disease would require different searches in the scientific literature.

In addition, if Group IV is elected, Applicant is further required to elect a specific method of suppressing the immune system comprising administering a specific caspase-8 inhibitor wherein the specific modification at the C-terminus of caspase-8 inhibitor comprises modification recited in claim 16.

These species are distinct because the specific method of suppressing the immune system comprising administering a specific caspase-8 inhibitor differ with respect to the specific caspase-8 inhibitor thus each specific method employing a specific caspase-8 inhibitor represents patentably distinct subject matter. Furthermore, the examination of specific caspase-8 inhibitor wherein the specific modification at the C-terminus of caspase-8 inhibitor comprises modification recited in claim 16 in the method of treating a tumor disease would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

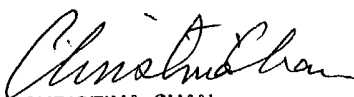
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 26, 2004

  
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